FT PharmaSuite®

NON-FUNCTIONAL REQUIREMENTS
RELEASE 11.01.00
FUNCTIONAL REQUIREMENT SPECIFICATION

Rockwell Automation

FT PharmaSuite® 11.01.00 - Functional Requirement Specification Non-functional Requirements

Contents

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1 Introduction

This document details the non-functional requirements of PharmaSuite.

Each requirement is composed of a name (e.g., Performance of Printing) and a unique identifier (e.g., GID-1234567) and is extended with its business attributes (GxP Relevance, Business Impact) and its compliance attribute (21 CFR Part 11 Relevance).

In some cases, additional context information is available, indicated in the document by a frame and a gray background color. This context information is related to the respective requirement, but not part of the formal requirement description.

The revision history lists the changes made to the document with the previous FactoryTalk PharmaSuite release as the comparison baseline. It provides individual tables for "Updated", "Added", and "Deleted" requirements that juxtapose the previous approved version with the new approved version of an item.

Typographical Conventions

This documentation uses typographical conventions to enhance the readability of the information it presents. The following kinds of formatting indicate specific information:

Bold typeface	Designates user interface texts, such as
	- window and dialog titles - menu functions - panel, tab, and button names - box labels - object properties and their values (e.g., status).

2 Performance Requirements (SR1095.10+)

The detailed list of the PharmaSuite performance requirements is structured in the following sections:

- **Master Recipe - Performance (SR1095.10.4+)** requirements (GID-2665900)
- **Change Request - Performance (SR1095.10.1+)** requirements (GID-2665907)
- **Equipment - Performance (SR1095.10.2+)** requirements (GID-2665911)
- **Recipe Execution - Performance (SR1095.10.7+)** requirements (GID-2665916)
- **Printing of Barcode Label and Dispensing Report - Performance** requirements (GID-2665918)
- **EBR Server - Performance (SR1095.10.3+)** requirements (GID-2665920)
- **TOM Server - Performance (SR1095.10.5+)** requirements (GID-2665922)
- **Exception Dashboard - Performance (SR1095.10.8+)** requirements (GID-2665924)

For performance requirements of phase building blocks, please refer to

- **Show historical data chart** phase in "Functional Requirement Specification Equipment Automation Phases" [A5] (GID-2666025).
- **Set OPC values** phase in "Functional Requirement Specification Equipment Automation Phases" [A5] (GID-2666025).
- **Get OPC values** phase in "Functional Requirement Specification Equipment Automation Phases" [A5] (GID-2666025).

2.1 Master Recipe - Performance (SR1095.10.4+)

For details about recipe management, see "Functional Requirement Specification Recipe and Workflow Management" [A1] (GID-2666025).

Reference scenario 1

The reference recipe holds a total of:

- 3 unit procedures,
- 5 operations,
- 20 phases, and
- 100 process parameters.

Boundary scenario 1

The boundary recipe holds a total of:

- up to 30 unit procedures,

- up to 35 operations,

- up to 3,000 phases, and

- up to 12,000 process parameters.

Its procedural structure includes various branches and loops.

2.1.1 GID-2665901 Performance of Master Recipe Import 1 (SR1095.10.4.1)

Based on the Boundary scenario 1 (GID-2665900), the import of the boundary recipe does not take longer than 10 minutes.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.1.2 GID-2665902 Performance of Master Recipe Export 1 (SR1095.10.4.2)

Based on the Boundary scenario 1 (GID-2665900), the export of the boundary recipe does not take longer than 10 minutes.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.1.3 GID-2665903 Performance of Master Recipe Saving 1 (SR1095.10.4.3)

Based on the Boundary scenario 1 (GID-2665900), saving the boundary recipe does not take longer than 10 seconds.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.1.4 GID-2665904 Performance of Prepare for Status Change 1 (SR1095.10.4.6)

Based on the Boundary scenario 1 (GID-2665900), the preparation of a status transition from **Draft** to **Verification** of a master recipe or master workflow does not take longer than 20 seconds.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.1.5 GID-2665905 Performance of Master Recipe Report 1 (SR1095.10.4.5)

Based on the Reference scenario 1 (GID-2665900), the response time for printing the Master Recipe Report of the reference recipe in the **Verification** status (time between "trigger the print function" and "display of the preview") does not take longer than 1 minute.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.1.6 GID-2665906 Performance of Order Explosion 1 (SR1095.10.4.4)

Based on the Boundary scenario 1 (GID-2665900), the order explosion of a boundary recipe-related order does not take longer than 1 minute.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.2 Change Request - Performance (SR1095.10.1+)

> For details about change requests, see "Functional Requirement Specification Recipe and Workflow Management" [A1] (GID-2666025)..

Reference scenario 1

For the performance test of the change request, the scope of the reference scenario is defined by replacing a **ShowSOP** custom phase within a total of 100 affected reference recipes.
The reference recipe is built with a total of 10 unit procedures, 22 operations, and 192 phases.

The recipe structure is as follows:

- 4 parallel Dispense unit procedures

  Each with 1 Dispense operation

  - Each with 9 phases

  - Incl. 1 phase based on the **ShowSOP** custom phase

- ▪ 6 subsequent processing unit procedures

  Each with 3 subsequent operations

  - ▪ 2 operations
    Each with 3 subsequent phases
    Incl. 1 phase based on the **ShowSOP** custom phase

  - ▪ 1 operation
    20 subsequent phases
    Incl. 4 phases based on the **ShowSOP** custom phase

Each procedure, unit procedure, and operation of the master recipe is built based on a custom building block in the **Approved** status. In total, 2 custom unit procedures, 4 custom operations, and 14 custom phases are used.

Boundary scenario 1

For the boundary test of the change request, the scope of the boundary scenario is defined by replacing a **ShowSOP** custom phase within a total of 1000 affected reference recipes.

2.2.1 GID-2665908 Performance of Change Request Execution 1 (SR1095.10.1.1)

Based on the Reference scenario 1 (GID-2665900), the execution of the change request does not take longer than 40 minutes.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.2.2 GID-2665909 Performance of Change Request Execution 2 (SR1095.10.1.2)

Based on the Boundary scenario 1 (GID-2665900), the execution of the change request is completed without any system errors.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.2.3 GID-2665910 Performance of Usage List Creation 1 (SR1095.10.1.3)

Based on the Boundary scenario 1 (GID-2665900) the initial creation of the usage list within the change request is completed within 80 seconds.

The expected response time is based on the following assumptions:

- ▪ All recipes that already existed in the database before the reference scenario was created (100 new recipes), are already indexed.

- Along with the creation of the usage list, new indexes are created only for the new recipes of the reference scenario.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3 Equipment - Performance (SR1095.10.2+)

> For details about equipment management, see "Functional Requirement Specification Data Management" [A2] (GID-2666025).

Reference scenario 1

For the performance test of the equipment management functionality, a reference equipment model is considered with a total of 230 classes, 5,000 entities, and 4,225 property types.

The model is structured as follows:

- Units, each with 67 properties

- Filters, hoses, instruments, each with 15 properties

- Number of class-entity-assignments and used property types
  (assumption: re-usage of property types between same type of classes of 50 %):

  100 unit classes, each with 10 entities

  - Based on 3,250 property types

  10 filter classes, each with 100 entities

  - Based on 75 property types

  20 hose classes, each with 50 entities

  - Based on 150 property types

  100 instrument classes, each with 20 entities

  - Based on 750 property types

Boundary scenario 1

For the boundary test of the equipment management functionality, the reference scenario is scaled up completely by a factor of 10, which means 2,300 classes, 50,000 entities, 42,250 property types.

Update scenario 1

Based on Reference scenario 1 (GID-2665900), an update rate per day of 1 % is assumed, which means that, e.g. 50 entities are updated per day with 1 runtime property being updated per entity. This results in:

- 18,250 change history entries per year,

- 36,500 change history entries after 2 years, and

- an average of 7-8 update-related change history entries per entity after 2 years.

Update scenario 2

Based on Reference scenario 1 (GID-2665900), an update rate per day of 10 % is assumed, which means that, e.g. 100 entities are updated per day with 5 runtime properties being updated per entity. This results in:

- 182,500 equipment logbook entries per year,

- 365,000 equipment logbook entries after 2 years, and

- an average of 73 update-related equipment logbook entries per entity after 2 years.

2.3.1 GID-2665912 Performance of Unit Class Export 1 (SR1095.10.2.1)

Based on Reference scenario 1 (GID-2665900), the export of 1 unit class does not take longer than 5 seconds.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3.2 GID-2665913 Performance of Unit Class Import 1 (SR1095.10.2.2)

Based on Reference scenario 1 (GID-2665900), the import of 1 unit class does not take longer than 5 seconds for an initial import.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3.3 GID-2665914 Performance of Filter Class Export 1 (SR1095.10.2.5)

Based on Reference scenario 1 (GID-2665900), the export of 1 filter class does not take longer than 15 seconds.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.3.4 GID-2665915 Performance of Filter Class Import 1 (SR1095.10.2.6)

Based on Reference scenario 1 (GID-2665900), the import of 1 filter class does not take longer than 15 seconds for an initial import.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.4 Recipe Execution - Performance (SR1095.10.7+)

> For details about the execution with PharmaSuite, see "Functional Requirement Specification Execution Framework" [A3] (GID-2666025).

Reference scenario 1

The reference recipe holds a total of:

- 1 Dispense unit procedure,

- 1 Dispense operation

- All Dispense-related phases (D Identify material, D Select scale, D Tare, D Weigh, D Release scale, D Print report)

- 10 materials to be dispensed

Boundary scenario 1

The boundary recipe holds a total of:

- up to 30 unit procedures,

- up to 35 operations,

- up to 3,000 phases, and

- up to 12,000 process parameters.

Its procedural structure includes various branches and loops.

2.4.1 GID-2665917 Performance of Recipe Execution 1 (SR1095.10.7.1)

Based on the Boundary scenario 1 (GID-2665900) and phase completion through automated test, the related control recipe is executable within 60 minutes.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.5 Printing of Barcode Label and Dispensing Report - Performance

For details about the barcode labels, see "Functional Requirement Specification Runtime Data Management" [A7] (GID-2666025), "Functional Requirement Specification Dispense and Inline Weighing" [A8] (GID-2666025), and "Functional Requirement Specification Output Weighing" [A9] (GID-2666025).

For details about the dispensing report, see "Functional Requirement Specification Dispense and Inline Weighing" [A8] (GID-2666025).

2.5.1 GID-2665919 Performance of Printing (SR1090.4.6)

Printing a barcode label does not take longer than 3 seconds (on average) and less than 5 sec (in 80% of the cases).

A reference Dispensing report contains of four pages and the reference printer prints at least 15 pages per minute.
Based on the reference report, printing the Dispensing report does not take longer than 30 seconds (in the average) and less than 60 seconds (in 80% of the cases).

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.6 EBR Server - Performance (SR1095.10.3+)

For details about the execution with PharmaSuite, see "Functional Requirement Specification Execution Framework" [A3] (GID-2666025).

Reference scenario 1

For the performance test of the EBR server, the reference scenario is as follows:

- Size of recipe:

  4 unit procedures (2 parallel)

  Each with 4 operations (2 parallel)

- Order explosion and order execution take place in parallel

- ▪ 50 Production Execution Clients

- ▪ 500 orders (10 sequential orders per client)

The focus of the performance test is on the behavior of the EBR server. Therefore, the execution of operations is performed as a virtual execution on a virtual client, which results in a zero second response time from a client.

2.6.1 GID-2665921 Performance of Order Processing 1 (SR1095.10.3.1)

Based on Reference scenario 1 (GID-2665900), the EBR server is capable to process 500 orders in less than 50 minutes (10 orders or 160 operations per minute).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.7 TOM Server - Performance (SR1095.10.5+)

For details about the execution with PharmaSuite, see "Functional Requirement Specification Execution Framework" [A3] (GID-2666025).

Reference scenario 1

For the performance test of the TOM server, the reference scenario is as follows:

- ▪ Test case includes:

    3 times start and removal of ETO templates

    10 times start and completion of ETO runs

    10 times escalation and expiration of ETO runs

- ▪ Scale-up consists of:

    50 Production Execution Clients running in parallel, all connected to the same TOM server

    10 consecutive runs of the test case on each client

The reference scenario results in a total of

- ▪ 1,500 ETO templates,

- ▪ 5,000 completed ETO runs, and

- ▪ 5,000 expired ETO runs,

that are managed by the TOM server.

The focus of the performance test is on the behavior of the TOM server. Therefore, the execution of operations is performed as a virtual execution on a virtual client, which results in a zero second response time from a client.

2.7.1 GID-2665923 Performance of ETO Processing 1 (SR1095.10.5.1)

Based on Reference scenario 1 (GID-2665900), the TOM server is capable to process ETO templates and runs in less than 30 minutes (50 templates per minute, 330 completed and expired runs per minute).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.8 Exception Dashboard - Performance (SR1095.10.8+)

For details about the Exception Dashboard, see "Functional Requirement Specification Review and Approval" [A4] (GID-2666025).

Reference scenario 1

The reference recipe holds a total of:

- 3 unit procedures,

- 5 operations,

- 20 phases, and

- 100 process parameters.

2.8.1 GID-2665925 Performance of Review by Exception 1 (SR1095.10.8.1)

Based on the Reference scenario 1 (GID-2665900) and a finished order, opening a unit procedure with 50 exceptions within the Details panel does not take longer than 50 seconds.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

2.8.2 GID-2665926 Performance of Batch Report Printing 1 (SR1095.10.8.2)

Based on the Reference scenario 1 (GID-2665900), the response time for printing the Batch Report of a finished order (time between "trigger the print function" and "display of the preview") does not take longer than 1 minute.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

3 Scalability Requirements (SR1095.30+)

3.1 GID-2665928 EBR Server - Scalability (SR1095.30.1)

The system shall provide the ability to distribute the workload to one or several EBR Servers.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

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4 Compliance Requirements (SR1095.50+)

> The detailed list of the PharmaSuite compliance requirements is structured in the following sections:
>
> - **Audit Trail (SR1095.50.1)** requirements (GID-2665930)
> - **Electronic Signatures (SR1095.50.2)** requirements (GID-3083512)
> - **Access Control (SR1095.50.3)** requirements (GID-2665936)

4.1 GID-2665930 Audit Trail (SR1095.50.1)

The system shall provide functionality for audit trail.

The following data shall be included as part of any human-readable form of an audit trail record:

- Transaction type (insert, update, delete).
- Timestamp.
- Logged-in user (login name, first and last name).
- Link to electronic signature(s), if applicable
- Transaction type-specific data (shall be defined for each transaction type)

> Audit trail data is available for:
>
> - Users, **Audit Trail (SR1095.50.3.2.1)** requirement (GID-2666414)
> - User groups, **Audit Trail (SR1095.50.3.3.1)** requirement (GID-2666427)
> - Access privileges, **Audit Trail (SR1095.50.3.4.1)** requirement (GID-2666430)
> - Lists, **Audit Trail (SR1095.9.1.1)** requirement (GID-2665946)
> - Applications, **Audit Trail (SR1095.9.2.1)** requirement (GID-2665954)
> - Materials, **Audit Trail (SR3146.1.1.5)** requirement in "Functional Requirement Specification Data Management" [A2] (GID-2666025)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.2 GID-3083512 Electronic Signatures (SR1095.50.2)

The system shall support electronic signatures.
For electronics signature in the context of EBR and the Production Execution Client, see **Signatures for Exceptions and Comments (SR1079.2.1)** and **Signature for Phase Completion (SR1089.4+)** in "Functional Requirement Specification Execution Framework" [A3] (GID-2666025).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.2.1 GID-2665932 Single and Double Electronic Signatures (SR1095.50.2.1)

The system shall support single and double electronic signatures. Double electronic signatures support the witness role.

When an electronic signature is required, the system shall request the user to authenticate with his user name and password. In case of a double electronic signature, two consecutive electronic signatures are required from two different users.

Whether a single or a double electronic signature is required shall be defined in the system configuration or during recipe or workflow definition.
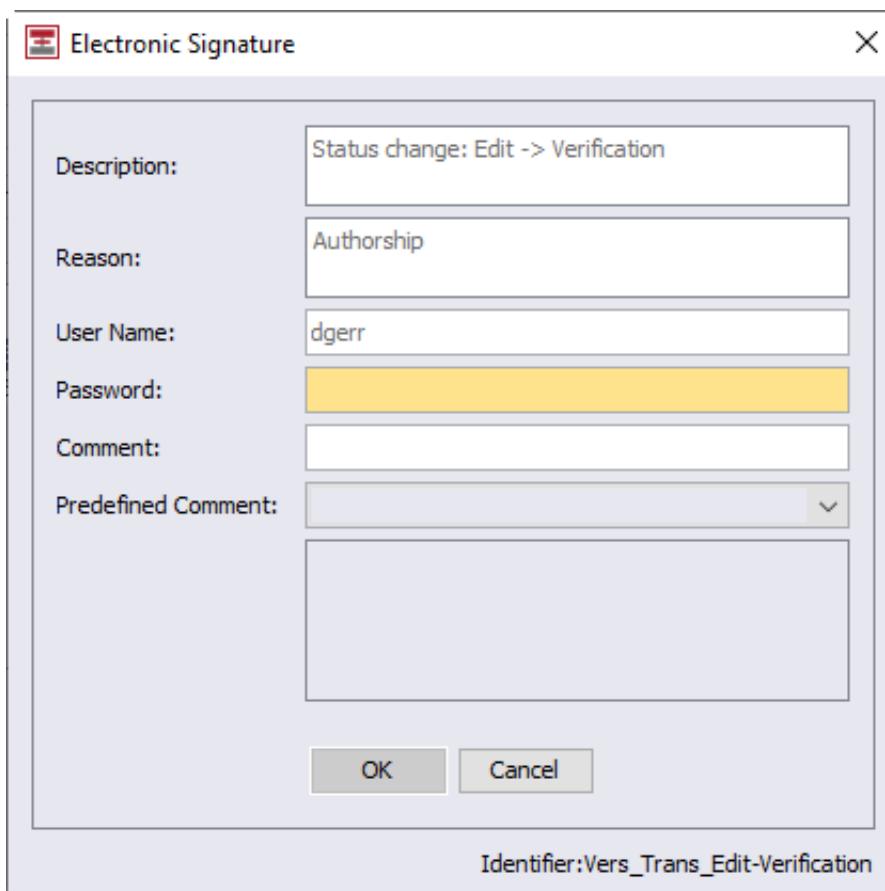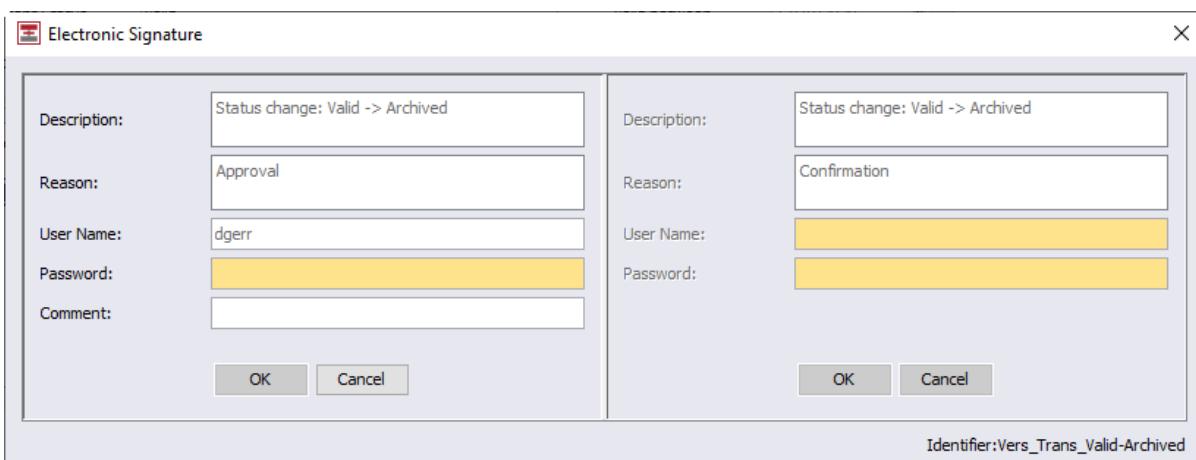
Figure 1: Example of a single electronic signature with pre-defined comment

Figure 2: Example of a single electronic signature with pre-defined comment

> For electronic signatures, the authentication requires the login name and password of a user as used for system login.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.2.1.1 GID-2666405 COMMENTS (SR1095.50.2.1.1)

The system shall allow to enter a comment along with an electronic signature and to extend a comment by a pre-defined text.
This does not apply to phase completion signatures during execution in the Production Execution Client.

Whether a comment is mandatory, optional, or not supported shall be defined in the system configuration or during recipe or workflow definition.
Whether a comment is extendable by a pre-defined text shall be defined in the signature definition.

For signature comments of signatures that automatically trigger the creation of an exception, the system shall add a signature-related comment as an exception-related comment to the exception. The exception-related comment of a single (or first) signature is prepended with "Signature comment: ", the exception-related comment of the second signature of a double signature is prepended with "2nd signature comment: ".

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.2.1.2 GID-2666406 LINKAGE TO ELECTRONIC RECORD (SR1095.50.2.1.2)

The system shall ensure that the linkage of an executed electronic signature to the electronic records for which the signature was given is unambiguous and incorruptible.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.2.2 GID-2665933 Configuring Electronic Signatures (SR1095.50.2.2)

The system shall allow the system administrator and system integrator to configure the following parameters of an electronic signature:

- Signature type (single, double)

- Meaning of the signature (description)

- Required user role of the user who signs (reason)

- Comment (no comment, optional, mandatory)
  This does not apply to phase building blocks that are executed in the Production Execution Client.

- Pre-defined comment list
  Definition of the list of pre-defined texts to be appended to the comment when an electronic signature is given.
  By default, no list is defined.
  This does not apply to phase building blocks that are executed in the Production Execution Client.

- Entitled user group

- Signature level (disabled, implicit w/o warning, explicit, warning w/ implicit, error (= no way to proceed))
  This does not apply to phase building blocks that are executed in the Production Execution Client.

  With the **implicit w/o warning** level, the system supports silent electronic signatures.
    If configured, instead of requesting an electronic signature, the system shall record the logged-in user automatically.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.2.3 GID-2665934 Performing Electronic Signatures (SR1095.50.2.3)

When the system requests an electronic signature it shall unambiguously provide the signer with the following information:

- Meaning of the signature

- Required user role (e.g. Confirmation, Approval)

- Scope of the signature

- Comment (as defined for the signature):

   1. no comment

   2. optional comment

   3. mandatory comment

- Pre-defined comment
   The signature dialog allows to select a pre-defined text from the list configured for the signature (only if a list has been defined).

   If a list has been defined, the selection of a text is mandatory.

   If a list contains only one entry, this entry is pre-selected.

- In case the user is the second signer of a double signature, the data entered by the first signer must be visible for the second signer.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.2.4 GID-2665935 Data of an Electronic Signature (SR1095.50.2.4)

The system shall add the following data of a given electronic signature (single or double) to any human-readable form of the affected electronic record (e.g. printout, electronic display):

- Meaning of the signature

- Role of the user who signed

- Scope of the signature as seen by the signer (context data related to the signature)

- Signer, timestamp, and comment (if mandatory or provided by the user)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3 GID-2665936 Access Control (SR1095.50.3)

The system shall provide functionality for access control.

> For access control requirements of specific system parts (e.g. access rights for editing or viewing data in Data Manager), please refer to
>
> - "Functional Requirement Specification Execution Framework" [A3] (GID-2666025)
>
> - "Functional Requirement Specification Runtime Data Management" [A7] (GID-2666025)
>
> - "Functional Requirement Specification Review and Approval" [A4] (GID-2666025)
>
> - "Functional Requirement Specification Recipe and Workflow Management" [A1] (GID-2666025)
>
> - "Functional Requirement Specification Data Management" [A2] (GID-2666025)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.1 GID-2665937 Authentication for System Login and Electronic Signature (SR1095.50.3.1)

The system shall ensure that only users with sufficient privileges have access to the system and are allowed to perform an electronic signature.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.1.1 GID-2666407 VERIFICATION DURING AUTHENTICATION (SR1095.50.3.1.1)

The system shall perform the following verification checks:

- Login name belongs to a valid user account.

- Password is correct.

- Password has not expired.

- User account is activated.

- Maximum number of invalid authentication attempts is not exceeded.

- User has sufficient access privileges to access the application or perform the electronic signature.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.1.2 GID-2666408 INVALID AUTHENTICATION ATTEMPT (SR1095.50.3.1.2)

In case of an invalid authentication attempt, the system shall display system messages to the user that do not give any hints to a possible intruder.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.1.3 GID-2666409 LOGGING UNSUCCESSFUL AUTHENTICATION ATTEMPTS (SR1095.50.3.1.3)

The system shall log unsuccessful authentication (login and electronic signature) attempts.
It shall be possible to notify a dedicated responsible person (or persons) of the event. The configurable notification shall include the following information:

- Used login name (identification code).

- Change of user account status (when the number of invalid login attempts is reached).

- Description of unsuccessful authentication.
  Example: Attempt to authenticate with a locked account.

The used medium for notifications shall be e-mail.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.1.4 GID-2666410 NUMBER OF INVALID AUTHENTICATION ATTEMPTS EXCEEDED (SR1095.50.3.1.4)

In case the number of invalid authentication attempts of a user account is exceeded, any further authentication request shall be blocked by the system. The user must contact the system administrator to reset the number of invalid authentication attempts.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.1.5 GID-2666411 MULTIPLE LOGINS PER USER (SR1095.50.3.1.5)

The system shall allow that one user is logged in in more than one session at the same moment.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.1.6 GID-2666412 VIEWING SYSTEM ACCESS HISTORY (SR1095.50.3.1.6)

The system shall track system access of users.
It allows a user to view the users with the login (successful, invalid) and logout information. The information includes (but is not limited to) the following properties:

- Timestamp

- Login name

- Transaction type (login, logout, failed login)

- Database name

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.2 GID-2665938 Management of Users (SR1095.50.3.2)

The system allows the system administrator to define and manage users and their access privileges. This includes the assignment of a user-specific start form.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.2.1 GID-2666413 SEPARATION OF ACCESS PRIVILEGES FOR CREATING AND EDITING USERS (SR1095.50.3.2.11)

The system shall provide separate access privileges for creating and editing users.

> The access privileges are only available in PS Administration.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.2.2 GID-2666414 AUDIT TRAIL (SR1095.50.3.2.1)

The system allows a user to view audit trail data recorded for users.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.2.3 GID-2666415 DEFAULT USER ACCOUNT SETTINGS (SR1095.50.3.2.2)

The system shall allow the system administrator to define default settings for user accounts:

- Maximum number of invalid authentication attempts: [No limit, 1..10]
  Default: No limit.

- Password strength:

  Minimum length: [No limit, 1..10]
  Default: No limit.

  Minimum number of lowercase characters: [0..10]
  Default: 0

  Minimum number of uppercase characters: [0..10]
  Default: 0

  Minimum number of numeric characters: [0..10]
  Default: 0

  Minimum number of special characters: [0..10]
  Default: 0

The system shall use the following setting if the password is changed:

- Minimum number of previous passwords before reuse: 3

- Maximum length of new password: 32

The system shall use the following setting for password expiration notifications:

- Notification of password expiration at login: 7 days

The system shall use the following default settings if a new user account is created:

- Validity timeframe for user accounts: December 31, 9999

- Expiration for passwords: December 31, 9999

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.2.4 GID-2666416 MANDATORY ATTRIBUTES (SR1095.50.3.2.12)

The system shall force the system administrator to define a login name (user name), first name, last name, and password when creating a user account.

> First and last name are only mandatory in PS Administration.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.2.5 GID-2666417 UNIQUE LOGIN NAME (SR1095.50.3.2.3)

The system shall force the system administrator to define a unique login name when creating a user account.

> With a unique login name (identification code), the combination of it and a password is always unique.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.2.6 GID-2666418 IMMUTABLE LOGIN NAME (SR1095.50.3.2.4)

The system shall prevent that a login name of a user account can be changed after the account has been created.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.2.7 GID-2666419 VALIDITY TIMEFRAME (USER ACCOUNT) (SR1095.50.3.2.5)

The system shall allow the system administrator to define the date when a user account becomes invalid.
The system shall use default values for the end date of the validity timeframe as defined in the system configuration according to the **Default User Account Settings (SR1095.50.3.2.2)** requirement (GID-2666415).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.2.8 GID-2666420 ACTIVITY STATUS (USER ACCOUNT) (SR1095.50.3.2.6)

The system shall allow the system administrator to activate and deactivate a user account.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.2.9 GID-2666421 NUMBER OF INVALID AUTHENTICATION ATTEMPTS (SR1095.50.3.2.7)

The system shall allow the system administrator to define how many false authentication attempts are allowed for user accounts before they are locked.
The system shall use default values for the maximum number of invalid authentication attempts as defined in the system configuration according to the **Default User Account Settings (SR1095.50.3.2.2)** requirement (GID-2666415)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.2.10 GID-2666422 PASSWORD STRENGTH (SR1095.50.3.2.8)

The system shall allow the system administrator to define the required password strength.
The system shall use the default values as defined in the system configuration according to the **Default User Account Settings (SR1095.50.3.2.2)** requirement (GID-2666415).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.2.11 GID-2666423 EXPIRY DATE (PASSWORD) (SR1095.50.3.2.9)

The system shall allow the system administrator to define an expiry date for the password of a user account.
The system shall use the rules for generating the password expiry date as defined in the system configuration according to the **Default User Account Settings (SR1095.50.3.2.2)** requirement (GID-2666415).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.2.12 GID-2666424 IMPORT/EXPORT OF USERS (SR1095.50.3.2.13)

The system shall provide the capability to transfer users between systems. For this purpose, it is possible to export and import users.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.2.13 GID-2666425 ASSIGNING USER GROUPS TO USERS (SR1095.50.3.2.10)

The system shall allow the system administrator to assign a user to one or multiple user groups and to revoke the assignment.
The system shall not limit the number of user groups to which a user can be assigned.
A user shall inherit the access privileges of the user group to which the user is assigned.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.3 GID-2665939 Management of User Groups (SR1095.50.3.3)

The system allows the system administrator to define and manage user groups and their access privileges, This includes the assignment of users to a user group.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.3.1 GID-2666426 SEPARATION OF ACCESS PRIVILEGES FOR CREATING AND EDITING USER GROUPS (SR1095.50.3.3.2)

The system shall provide separate access privileges for creating and editing user groups.

> The access privileges are only available in PS Administration.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.3.2 GID-2666427 AUDIT TRAIL (SR1095.50.3.3.1)

The system allows a user to view audit trail data recorded for user groups.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.3.3 GID-2666428 IMPORT/EXPORT OF USER GROUPS (SR1095.50.3.3.3)

The system shall provide the capability to transfer user groups between systems. For this purpose, it is possible to export and import user groups.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.4 GID-2665940 Separation of User and Functional System Administration (SR1095.50.3.7)

The system allows the separation of the user and user group administration from the functional system administration (configuring access privileges and their assignment to user groups, configuring lists and applications). This is a configurable option per system installation.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.5 GID-2665941 Management of Access Privileges (SR1095.50.3.4)

The system allows the system administrator to define and manage access privileges (access rights and electronic signatures including their signature definition). This includes the assignment of privileges to user groups.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.5.1 GID-2666429 SEPARATION OF ACCESS PRIVILEGES FOR CREATING AND EDITING ACCESS PRIVILEGES (SR1095.50.3.4.6)

The system shall provide separate access privileges for creating and editing access privileges.

The access privileges are only available in PS Administration.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.5.2 GID-2666430 AUDIT TRAIL (SR1095.50.3.4.1)

The system allows a user to view audit trail data recorded for access privileges.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.5.3 GID-2666431 ACCESS PRIVILEGES FOR PRE-DEFINED SET OF FUNCTIONS (SR1095.50.3.4.2)

The system shall provide access privileges for a set of pre-defined functions.
This set of functions shall be extendable by a system integrator.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.5.4 GID-2666432 PRE-DEFINED ROLES AND PROFILES (SR1095.50.3.4.3)

The system shall provide a set of pre-defined roles, mapped to user groups, with pre-defined access privileges according their assigned profiles.
This set of user groups and access privileges shall be changeable and extendable by a system integrator.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.5.5 GID-2666433 IMPORT/EXPORT OF ACCESS PRIVILEGES (SR1095.50.3.4.7)

The system shall provide the capability to transfer access privileges between systems. For this purpose, it is possible to export and import access privileges.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.5.6 GID-2666434 VIEWING ACCESS PRIVILEGES OF USERS OR USER GROUPS (SR1095.50.3.4.4)

The system allows a user to view the access privileges of a user or user group at any defined moment.

> This moment can be in the past until the present time.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.5.7 GID-2666435 VIEWING USERS OR USER GROUPS OF ACCESS PRIVILEGES (SR1095.50.3.4.5)

The system allows a user to view the users or user groups of an access privilege at any defined moment.

> This moment can be in the past until the present time.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.6 GID-2665942 Password Security (SR1095.50.3.5)

The system shall ensure confidentiality of passwords that are managed in the system.
Only the related person shall know his personal password.

An exception is the initial password.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.6.1 GID-2666436 PASSWORD ENCRYPTION (SR1095.50.3.5.1)

The system shall fulfill the following items related to password encryption:

- Passwords are always stored encrypted.

- The system must not provide a function to decrypt an encrypted password. The encryption is a one-way encryption.

- The system encrypts passwords that need to be sent over a network that can be accessed by other users.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.6.2 GID-2666437 PASSWORD MUST NOT BE DISPLAYED (SR1095.50.3.5.2)

The system shall never display a password in plain text on any kind of user interface including printouts.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.7 GID-2665943 Password Change (SR1095.50.3.6)

The system shall support that the password can be changed.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

4.3.7.1 GID-2666438 PASSWORD CHANGE – USER-INITIATED (SR1095.50.3.6.1)

The system shall provide functionality for the user to change his password. The system requests the user to enter his old password and the new password twice. The new password shall fulfill the password requirements as defined in the system configuration according to the **Default User Account Settings (SR1095.50.3.2.2)** requirement (GID-2666415).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.7.2 GID-2666439 PASSWORD CHANGE – AFTER LOGIN (SR1095.50.3.6.2)

The system shall allow a user to change the password directly after a successful login. This is important in case the password is going to expire within the next n days and the user needs to have the system available immediately.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

4.3.7.3 GID-2666440 PASSWORD CHANGE – SYSTEM-FORCED (SR1095.50.3.6.3)

In case the password has expired, the system shall force the user to change his password at login.
There shall be no possibility to access the system without changing the expired password.
The system requests the user to enter his old password and the new password twice. The new
password shall fulfill the password requirements as defined in the system configuration according to
the **Default User Account Settings (SR1095.50.3.2.2)** requirement (GID-2666415).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5 Functional System Administration (SR1095.9+)

> The functional system administration includes:
>
> - **List audit trail (SR1095.9.1.1)** requirement
> - **Application audit trail (SR1095.9.2.1)** requirement

5.1 GID-2665946 List Audit Trail (SR1095.9.1.1)

The system allows a user to view audit trail data recorded for lists.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

5.2 GID-2665954 Application Audit Trail (SR1095.9.2.1)

The system allows a user to view audit trail data recorded for application objects.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

6 Internationalization and Localization (SR1095.1+)

PharmaSuite is marketed globally. This requires the software to support internationalization (I18N) and localization (L10N).

Internationalization (I18N) is the process of planning and implementing products and services so that they can easily be adapted to specific local languages and cultures, a process called localization. The internationalization process is sometimes called translation or localization enablement.

Localization (L10N) is a process of adapting a product or service to a particular language, culture, and desired local "look-and-feel".

The requirements specific to internationalization and localization are structured in the following sections:

- **Skills for Localization (SR1095.1.1)** requirements (GID-2665958)

- **Locale-related** requirements (GID-2665961)

6.1 GID-2665958 Skills for Localization (SR1095.1.1)

The system shall be localizable into a specific language or terminology by a system integrator.

It shall be possible that a person used to work with office software without knowledge of the system or specific IT knowledge is able to modify choice lists contents and text labels of the user interface and reports. It shall be possible for a system integrator to export this information from the system. The result of the modification must be in a format that it can be integrated to the system by a system integrator.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.1 GID-2665959 Tool Support (SR1095.2.4)

The system shall provide tools that allow a system integrator to localize the user interface, reports, barcode labels, system messages, etc. for a particular language or terminology.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.1.2 GID-2665960 Internationalized Output Media (SR1095.2)

The system shall provide internationalization for those parts of the system that are presented to common users of the system, so that it is possible to localize them into a particular language or terminology. The user roles do not include system integrators, project engineers, etc.

The internationalized parts include the user interface, online help, reports, barcode labels, system messages, installation software, and user manuals. Internationalization is not limited to text but also includes data formats like date, time, and number formats.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2 Locale-related Requirements

A locale defines the regional settings with specific parameters. For example language of the user interface, keyboard layout, number format, date and time format, paper size.

6.2.1 GID-2665962 Supported Locales (SR1095.1.2)

The system shall support localization into the following locales (sequence not related to priority):

- English (United States) - Default

- German (Germany)

- Spanish (Spain-Modern Sort)

- Italian (Italy)

- French (France)

- Chinese (PRC)

- Korean

- Japanese

- Russian (Russia)

- Hebrew

- Hindi

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.2 Provided Locales (SR1095.2.3+)

6.2.2.1 GID-2666441 ENGLISH (UNITED STATES) (SR1095.2.3.1)

The default locale of the system shall be English (United States):

- Default date format: mm/dd/yyyy

- Default digit grouping symbol: , (comma)

- Default decimal separator: . (dot)

- Default time format: hh:mm:ss (AM/PM)

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.3 GID-2665964 Locales within One Installation (SR1095.2.1)

The system shall support multiple locales within one installation.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.4 GID-2665965 Choice of Locale (SR1095.2.2)

The system shall allow the user to choose the locale to be used at when logging on to the system.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

6.2.5 GID-2665966 Configurable Locale-specific Settings (SR1095.1.3)

The system shall allow the configuration of the following locale-specific settings:

- Date format

- Number format (digit grouping symbol and decimal separator)

- Time format

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7 Installation, Backup, and Upgrade (SR1095.4+)

7.1 GID-2665968 Installation of PharmaSuite (SR1095.4.1)

The system shall allow to be installed by system administrators.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

7.1.1 GID-2665969 Existing Database (SR1095.4.1.7)

The installation shall support installation into an existing database installation (other instances already installed on the database).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

7.1.2 GID-2665970 Installation Result (SR1095.4.1.8)

The installation shall inform the user if the installation was successful or not.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

7.1.2.1 GID-2666442 LOGGING OF INSTALLATION (SR1095.4.1.8.1)

The installation shall write all installation steps into a log file including the status of each step and, if applicable, the reason for failure.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

7.1.3 GID-2665971 Installation Manual (SR1095.4.1.4)

The system shall provide an installation manual that supports a system administrator when installing the system.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

7.2 GID-2665972 Backup (SR1075.6)

The system shall allow to backup data and system.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.2.1 GID-2665973 Backup of a Running System (SR1075.6.1)

The system shall allow to backup the data stored in the database during production time with an appropriate third-party backup tool. The backup does not include data in the local client's cache.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.2.2 GID-2665974 Backup and Restoring (SR1075.6.3)

It shall be possible to completely backup and restore both, system and data, with a third-party tool. The configuration and execution of the backup and restore environment is done by IT subject matter experts.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3 Upgrade Tool (SR1075.8+)

The system shall provide an upgrade tool to update the system and to migrate the data.

7.3.1 GID-2665976 Basic Upgrade Engine (SR1075.8.1)

The basic upgrade engine allows the upgrade of a PharmaSuite releases in five stages:

- Stage 1 verifies the completeness of the upgrade package.

- Stage 2 determines the planned changes required to upgrade from the base to the new version.

- Stage 3 checks the planned changes against the target system and reports non-resolvable conflicts as well as potential conflicts (based on project extensions).

- Stage 4 performs the system update and the data migration on the target system based on the results of stage 3.

- Stage 5 verifies the results of the upgrade process.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.1.1 GID-2666443 UPGRADE - CONTINUE EXECUTION (SR1075.8.3.5)

Along with the upgrade of the system to a following new software version, the system shall allow to execute and finish orders with the new release that originally have been started with the previous release.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2 System Update Tasks (SR1075.8.2+)

The upgrade tool shall provide the following system update tasks:

7.3.2.1 GID-2666444 UPDATE TASK FOR DSX OBJECTS (GENERIC DSX) (SR1075.8.2.1)

The upgrade tool shall support an update task for objects that are part of FactoryTalk ProductionCentre DSX format (generic DSX).

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.2 GID-2666445 UPDATE TASK FOR MESSAGE OBJECTS (SR1075.8.2.2)

The upgrade tool shall support an update task for message packs. The conflict handling shall be done on message ID level.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.3 GID-2667121 UPDATE TASK FOR EAR FILES (SR1075.8.2.3)

The upgrade tool shall support an update task for EAR artifacts.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.4 GID-2667122 UPDATE TASK FOR ATROW OBJECTS (SR1075.8.2.4)

The upgrade tool shall support an update task for ATRow artifacts.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.5 GID-2667123 UPDATE TASK FOR LIBRARY OBJECTS (SR1075.8.2.5)

The upgrade tool shall support an update task for library artifacts.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.6 GID-2667124 UPDATE TASK FOR IMAGE OBJECTS (SR1075.8.2.6)

The upgrade tool shall support an update task for image artifacts.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.7 GID-2667125 UPDATE TASK FOR FSM (FLEXIBLE STATE MODEL) OBJECTS (SR1075.8.2.7)

The upgrade tool shall support an update task for FSM artifacts.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.8 GID-2667126 UPDATE TASK FOR AT DEFINITION OBJECTS (SR1075.8.2.8)

The upgrade tool shall support an update task for AT Definition artifacts.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.9 GID-2667127 UPDATE TASK FOR UDA DEFINITION OBJECTS (SR1075.8.2.9)

The upgrade tool shall support an update task for UDA Definition artifacts.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.10 GID-2667128 UPDATE TASK TO REPORT CUSTOMER NOTIFICATIONS (SR1075.8.2.11)

The upgrade tool shall support an update task to report customer modifications.
This task shall only be applicable to **Stage 3** (Checking Target System for Conflicts) and create a report with the list of objects that have been added to, modified in, or deleted from the customer system.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.11 GID-2667129 UPDATE TASK FOR APPLICATION OBJECTS (SR1075.8.2.12)

The upgrade tool shall support an update task for Application artifacts.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.12 GID-2667130 UPDATE TASK FOR VERSIONING CONFIGURATION OBJECTS (SR1075.8.2.13)

The upgrade tool shall support an update task for Versioning Configuration artifacts.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.13 GID-2667131 UPDATE TASK FOR REPORT DESIGN OBJECTS (SR1075.8.2.14)

The upgrade tool shall support an update task for Report Design artifacts.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.2.14 GID-2667132 UPDATE TASK FOR ACCESS PRIVILEGE OBJECTS (SR1075.8.2.15)

The upgrade tool shall support an update task for Access Privilege artifacts.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.3 System Update and Data Migration Packages (SR1075.8.3+)

The upgrade tool shall provide system update and data migration packages specific to a PharmaSuite version.

7.3.3.1 GID-2667133 SYSTEM UPDATE FROM THE PREVIOUS SOFTWARE VERSION (SR1075.8.3.25)

The system update package shall allow to update a PharmaSuite system from the previous software version to the subsequent software version by applying functional and structural changes and adding new functions.

For an overview of the default system update tasks, please refer to the **System Update Tasks (SR1075.8.2**+) requirement (GID-2665977)

For a system update from PharmaSuite 11.00.00 to PharmaSuite 11.01.00, no specific system update tasks are available.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.3.2 GID-2667134 DATA MIGRATION FROM THE PREVIOUS SOFTWARE VERSION (SR1075.8.3.26)

The data migration package shall allow to migrate specific data that already resided in a previous software version of PharmaSuite to be suitable for use with the new or changed system functions of the subsequent software version.

For a data migration from PharmaSuite 11.00.00 to PharmaSuite 11.01.00, no specific data migration tasks are available.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.3.4 Extensibility (SR1075.8.5+)

7.3.4.1 GID-2667135 UPGRADE PACKAGES (SR1075.8.5.1)

The system upgrade tool shall allow a system integrator to adapt system update and data migration packages, so that customized releases of PharmaSuite can be upgraded with the extended upgrade packages.

This extension use case shall be documented and informally tested.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

7.4 GID-2665980 Pre-install Configuration (SR3146.7)

The system shall support specific pre-install configurations by a system integrator.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

8 GID-2665981 General Client Framework (SR3071.1)

The system shall support general client framework capabilities.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9 User Experience (SR1095.5+)

9.1 GID-2665989 Messages (SR1095.5.1.1)

The system shall display only meaningful system and error messages to the user.
Pure technical messages shall be avoided.

Example: The operator is generally not interested that a unique constraint in a database table is violated, but that the batch identifier is not unique.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

9.2 Device-specific Usability (SR1095.5.1.4+)

9.2.1 GID-2665991 Touch Screen (SR1095.5.1.4.2)

The system shall provide a user interface for the Production Execution Client that allows to operate the system via touch screen.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

9.2.2 GID-2665992 Virtual Keyboard (SR1095.5.1.4.2.1)

As an EBR operator I need to be able to enter data via a virtual keyboard ("soft keyboard"), so that I can operate the system via touch screen only.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

9.3 GID-2665993 Look and Feel (SR1095.5.7)

The Look and Feel of the system shall be state-of-the-art.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

9.3.1 GID-2665994 GUI Design (SR1095.5.7.3)

The GUI shall be designed in a way that supports easy readability of key information, in support of the special needs of the operator. This includes structure, design and sizing of forms and panels.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

9.3.2 GID-2665995 GUI Adaptation (SR1095.5.7.1)

The user interface of PharmaSuite shall be adaptable by simple means, allowing to adjust colors, fonts, and font sizes.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

9.3.3 GID-2665996 Dialog Boxes (SR1095.5.7.2)

The dialog boxes used within PharmaSuite shall all have a common appearance in terms of colors, fonts, and button style.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

9.3.4 GID-2665997 Grid Components (SR1095.5.7.4)

The system shall support state-of-the-art grid components. When functionally suitable, this includes:

- sorting by rows,

- manual adjustment of sequence of columns, and

- support of multi-selection (per configuration).

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

9.3.5 GID-2665998 Reset User-specific Layout (SR1095.5.7.5)

The system shall allow the system administrator to reset a user-specific layout to the default layout of the respective client.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

9.4 Extensibility (SR1095.5.1.2+)

9.4.1 GID-2666000 System - Customization (SR1095.5.1.2.1)

The system shall be customizable in a way that a system integrator is able to:

- add or modify workflows,

- add, remove, or modify data object attributes,

- add, remove, or modify fields and labels of the user interface,

- rename labels of the user interface, and

- add, remove, or modify reports and barcode labels.

It must be possible to perform the modifications "offline" in a development system and to integrate them into an existing customer system. The respective guidelines shall be documented in Technical Manuals.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.2 GID-2666001 System - View Model-related Objects (SR1095.5.1.2.3)

The system shall allow a system integrator to add attributes to a view model-related object without the need of Java coding.
This extension use case shall be documented and tested.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.3 GID-2666002 System - Material Attribute (SR1095.5.1.2.9)

The system shall allow a system integrator to add a material/batch attribute across the system and to implement business logic that makes use of this attribute.
This extension use case shall be documented and informally tested. Testing shall be based on the example of a **Second potency** attribute.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.4 GID-2666003 System - ERP BOM Attribute (SR1095.5.1.2.11)

The system shall allow a system integrator to add a new attribute to the ERP BOM, which is automatically populated into the related new attribute of the material parameter.
In case the same attribute also exists as material master data, the default value for the material parameter will be taken from the material master data in case no value exists in the ERP BOM.
This extension use case shall be documented and informally tested. Testing shall be based on the example of a **Second potency** attribute.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.5 GID-2666004 System - Batch Status (SR1095.5.1.2.10)

The system shall allow a system integrator to add a batch status to the flexible state model (FSM) and to implement business logic that makes use of the new status.
This extension use case shall be documented and informally tested. Testing shall be based on the example of a **Conditionally released** status of a batch.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.6 GID-2666005 Master Recipe - Approval Workflow (SR1095.5.1.2.13)

The system shall allow a system integrator to adapt the approval workflow of a master recipe according to project needs. This includes the ability to

- add a new status that has the same semantic meaning as one of the given **Edit** and **Verification** statuses,

- adjust status transitions accordingly, and

- rename statuses and status transitions (actions).

This extension use case shall be documented and informally tested.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.7 GID-2666006 Expression Editor - Context Data (SR1095.5.1.2.14)

The system shall allow a system integrator to enhance the context data-related capability of the Expression editor. This includes the ability to

▪ add a new attribute to the list of available attributes for a given object-related function and

▪ add a new function to access the context data of a new object.

This extension use case shall be documented and informally tested.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.8 GID-2666007 Building Block - Name Spaces (SR1095.5.1.2.4)

The system shall support the deployment of building blocks from different system integrators by definition of name spaces.
This extension use case shall be documented and tested.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.9 GID-2666008 Building Block - Mainstream GUI Programming (SR1095.5.1.2.6)

For the implementation of a GUI of a System Building Block, the system shall support mainstream Java GUI programming mechanisms, rather than being dependent on proprietary components.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.10 GID-2666009 Master Recipes, Master Workflows, and Custom Building Blocks - Comparison (SR1095.5.1.2.17)

The system shall allow a system integrator to extend the comparison functionality (see chapter "**Comparing Master Recipes, Master Workflows, and Custom Building Blocks (SR3146.15**+)" in the "Functional Requirement Specification Recipe and Workflow Management" [A1] (GID-2666025), in regards of customized data structures referencing the master recipe. (Directly extended master recipe data structures such as process parameters are not included here).

> For details, see chapter "Extending Comparison in Recipe and Workflow Designer" in Volume 3 of the "Technical Manual Configuration and Extension" [A6] (GID-2666025).

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.11 GID-2666010 Execution - Autostart (SR1095.5.1.2.2)

For a system integrator, the system shall allow to configure specific activity sets that are started automatically upon start of the Production Execution Client. One activity set can be started multiple times in case multiple instances are allowed for this activity set (configurable).

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.12 GID-2666011 Execution - Select Order Grid (SR1095.5.1.2.5)

For the **Select order** grid of the Batch or Workflow Processing actions of the Cockpit, the system shall allow a system integrator to add project-specific fields/columns to the grid and to adjust the pre-defined filter criteria, according to project-specific business rules.
This extension use case shall be documented and tested.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.13 GID-2666012 Execution - EBR Header Bar (SR1095.5.1.2.8)

The system shall allow a system integrator to change the content of the EBR header bar of the Production Execution Client.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.14 Reporting (SR1095.5.1.2.16+)

9.4.14.1 GID-2667136 MASTER RECIPE REPORT VARIANTS (SR1095.5.1.2.16.1)

The system shall allow a system integrator to create and print a master recipe report variant from Recipe Designer in addition to the standard master recipe report.
This extension use case shall be documented and informally tested.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.14.2 GID-2667137 MASTER WORKFLOW REPORT VARIANTS (SR1095.5.1.2.16.2)

The system shall allow a system integrator to create and print a master workflow report variant from Workflow Designer in addition to the standard master workflow report.
This extension use case shall be documented and informally tested.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.14.3 GID-2667138 BATCH REPORT VARIANTS (SR1095.5.1.2.16.3)

The system shall allow a system integrator to create and print a batch report variant from the Production Management Client and the Production Response Client in addition to the standard batch report.
This extension use case shall be documented and informally tested.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.14.4 GID-2667139 WORKFLOW REPORT VARIANTS (SR1095.5.1.2.16.4)

The system shall allow a system integrator to create and print a workflow report variant from the Production Management Client in addition to the standard workflow report.
This extension use case shall be documented and informally tested.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.15 GID-2666014 Receive Material Data - Key Tags for Barcoded Information (SR1076.22)

The system shall allow a system integrator to define the key tags that serve to distinguish barcodes for different data objects.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.16 GID-2667140 Concatenated Information (SR1076.23)

The system shall allow a system integrator to configure at least three different barcode definitions that concatenate batch, material sublot, material number, and sublot quantity information.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.17 GID-2667141 Sublot (SR1076.24)

The system shall allow a system integrator to configure at least one barcode format that contains a sublot identifier.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.4.18 GID-2667142 Batch (SR1076.25)

The system shall allow a system integrator to configure at least one barcode format that contains a batch identifier.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.5 Precision of Numerical Data (SR1095.5.1.3+)

9.5.1 GID-2666016 Fixed Point Numbers (SR1095.5.1.3.1)

The system shall support decimal fixed-point numbers for the definition of input and output parameters to support the control of scaling of decimal values.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.5.2 GID-2666017 Floating Point Arithmetic (SR1095.5.1.3.2)

For calculations, the system shall use decimal floating point arithmetic that is compliant to the IEEE 754R standard.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.5.3 GID-2666018 Errors at Calculation (SR1095.5.1.3.3)

Errors at calculation (division by zero, overflow, underflow, inexact, invalid operation), as defined in the IEEE 754R standard, shall be reported by the system.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.5.4 GID-2666019 Input Data Errors (SR1095.5.1.3.4)

The system shall not consider input data errors at calculation, i.e. the scale of a calculation result is not adapted by the system. The correct setting of the scale of a calculation result lies within the responsibility of the system user.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.5.5 GID-2666020 Rounding (SR1095.5.1.3.5)

At rounding, the following method shall apply (round-half-up): if the discarded digits are greater than or equal to a half (0.5) of a one in the next left position then the result coefficient shall be incremented by 1 (rounded up) - otherwise the discarded digits are ignored.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.6 Input Length Limitations (SR1095.5.1.8+)

Depending on the used character encoding, string input fields allow different numbers of characters. A maximum length definition of a string field always refers to single-byte encoding.

9.7 GID-2666022 Concurrent Data Access - Pessimistic Locking (SR1095.5.1.5)

Concurrent data access shall not lead to data inconsistency.
The system shall support pessimistic locking mechanisms.

Example:
Record 1 is locked by user 1; user 1 has read and write rights.
For user 2, who comes later than user 1, the system assures that user 2 cannot modify or delete the locked record.

In the Production Management Client and Recipe and Workflow Designer, the system still allows user 2 to read the record while it is locked by user 1.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.8 GID-2666023 Restart and Recovery (SR1095.8)

The system shall support "save points".
At a save point, the system generates consistent data in the system accessible by other users and functions.

The default save points are defined in the application. They are not configured nor shall be configurable. The locations of the save points are defined in the requirements of the respective pre-defined workflows. In case of a system breakdown, all modifications done up to there are rolled back if no save point has been reached in the respective workflow.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	Medium
MES-Compliance: 21 CFR Part 11 relevance	No

9.8.1 GID-2666024 Client Data Consistency after Database Server Reconnect (SR1095.8.1)

In case a client loses its database server connection, after reestablishing the connection, the system shall ensure that the client operates with the same data as available in the database.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.9 GID-2665982 System Login (SR3071.1.1)

The system shall enforce user login.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

9.10 GID-2665983 System Exit (SR3071.1.3)

The system shall provide a function to exit the system in a controlled manner. The system shall check if there is any unsaved data and shall warn the user if that is the case.
Before shutting down the system it shall warn the user that it is going to shut down and shall ask for confirmation.

Exiting the system means shutting down and ending all relevant system processes.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	Yes

9.11 GID-2665984 Unique Device (SR3071.1.5)

The system shall be able to identify the unique physical device that is used for accessing PharmaSuite. This applies to PharmaSuite running directly on a physical device or PharmaSuite running via remote access.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.12 GID-2665985 Unique Session of the Production Execution Client (SR3071.1.6)

For any given device, the system shall not allow to start another Production Execution Client (PEC) session of PharmaSuite.

Attribute	Value
MES-Business: GxP relevance	Yes
MES-Business: Business Impact	High
MES-Compliance: 21 CFR Part 11 relevance	No

9.13 GID-2665986 About Dialog (SR3071.1.7)

The system shall provide an About dialog for each client, which provides general information (e.g. version, logged-in user) and installation details (e.g. application server, application configuration).

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	Low
MES-Compliance: 21 CFR Part 11 relevance	No

9.14 GID-2665987 Online Help (SR3071.1.8)

If a client-specific help system is available, the system shall provide access to the client-specific help system.

Attribute	Value
MES-Business: GxP relevance	No
MES-Business: Business Impact	None
MES-Compliance: 21 CFR Part 11 relevance	No

10 Reference Documents

The following documents are available from the Rockwell Automation Download Site.

No.	Document Title	Part Number
A1	FT PharmaSuite Functional Requirement Specification Recipe and Workflow Management	PSFRSRD-RM011B-EN-E
A2	FT PharmaSuite Functional Requirement Specification Data Management	PSFRSDM-RM007B-EN-E
A3	FT PharmaSuite Functional Requirement Specification Execution Framework	PSFRSEF-RM007B-EN-E
A4	FT PharmaSuite Functional Requirement Specification Review and Approval	PSFRSRA-RM007B-EN-E
A5	FT PharmaSuite Functional Requirement Specification Equipment Automation Phases	PSFRSEA-RM007B-EN-E
A6	FT PharmaSuite Technical Guide Configuration & Extension - Volume 3	PSCEV3-GR011B-EN-E
A7	FT PharmaSuite Functional Requirement Specification Runtime Data Management	PSFRSRT-RM007B-EN-E
A8	FT PharmaSuite Functional Requirement Specification Dispense and Inline Weighing	PSFRSDI-RM009B-EN-E
A9	FT PharmaSuite Functional Requirement Specification Output Weighing	PSFRSOW-RM005B-EN-E

TIP

To access the Rockwell Automation Download Site, you need to acquire a user account from Rockwell Automation Sales or Support.

11 Document Information

The document information covers various data related to the document.

11.1 Approval

This document has been approved electronically via the Rockwell Automation Document Management System (DMS). The required approvers of this document include the following:

Name	Role
Norbert Ern	Product Owner
Wolfgang Schmitt	Technical Lead
Ignaz Wangler	Test Lead

11.2 Version Information

Object	Version
FT PharmaSuite	11.01.00
Functional Requirement Specification	1.0

12 Appendix A - Revision History

12.1 Updated Requirements

GID-2665926 Performance of Batch Report Printing 1 (SR1095.10.8.2)

GID-2666440 Password Change – System-forced (SR1095.50.3.6.3)

GID-2667133 System update from the previous software version (SR1075.8.3.25)

GID-2667134 Data migration from the previous software version (SR1075.8.3.26)

12.2 Added Requirements

None

12.3 Deleted Requirements

None

FT PharmaSuite® 11.01.00 - Functional Requirement Specification Non-functional Requirements

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